1651

PATENT
Attorney Docket No. 24512-X

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

REUSER et al. Examiner: J. Weber

Serial No.: 09/886,477 Art Unit: 1651

Filed: June 22, 2001

For: **METHODS OF PURIFYING HUMAN ACID ALPHA-GLUCOSIDASE**

TRANSMITTAL LETTER

Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

1) Transmittal Letter;
2) Response to Restriction Requirement;
3) Petition for Three-Month Extension of Time; and
4) Check No. 8507 in the amount of $465.00.

The Commissioner is specifically authorized to charge any required fee deficiency under 37 CFR §§ 1.16 or 1.17, or credit any overpayment, to Deposit Account No. 14-0112 in connection with this matter.

Respectfully submitted,

NATH & ASSOCIATES PLLC

Date: Apr. 17, 2003

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#14
D.G.J
4/23/03

In re Application of:

REUSER et al. Examiner: J. Weber

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For: **METHODS OF PURIFYING HUMAN ACID ALPHA-GLUCOSIDASE**

RESPONSE TO RESTRICTION/ELECTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Official Action dated January 13, 2003. The one-month shortened statutory period for response was set to expire February 13, 2003. Accordingly, a Petition for Three-Month Extension of time is submitted herewith extending the period for reply to May 13, 2003.

SUMMARY OF RESTRICTION REQUIREMENT

The Examiner has required restriction of claims 1-37 under 35 U.S.C. 121 to a single invention encompassed by the claims as follows:

> Applicant's election with traverse of Group I, claims 1-10, 22, 36 and 37 in Paper No. 10, filed 01 November 2002 is acknowledged. The traversal is on the ground(s) that there is no burden between Groups I and II. It is believed that the restriction of 02 October 2002 was incorrectly presented. In view of the newly presented restriction, the election is rendered moot.
> Restriction to one of the following inventions is now required under 35 U.S.C. 121:
> I. Claims 1-19, drawn to a multistep method of

purifying human acid α-glucosidase (including heterologously produced in milk), classified in class 435, subclass 201.

II. Claims 20-25 and 27-28, drawn to human acid α-glucosidase and a method of making a medicament therefrom (by mixing), classified in class 435, subclass 201, and class 424, subclass 94.61.

III. Claim 26, drawn to a method of treating human acid α-glucosidase deficiency, classified in class 424, subclass 94.61.

IV. Claims 29-35, drawn to a single step method of purifying a heterologous protein, classified in class 435, subclass 183 and class 530, subclass 402+.

V. Claims 36-37, drawn to a single step method of purifying a human acid α-glucosidase, classified in class 435, subclass 201.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to substantially different processes: a multistep purification procedure for human acid α-glucosidase, a single step procedure for purifying a host of possible proteins, and a single step procedure for purifying human acid α-glucosidase respectively. The processes are substantially distinct from each other.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product could be made by any of a number of known methodologies including but not limited to steps set forth in Belen'kil et al. (1974).

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be used with another materially different product or (2) the product as claimed can be used in a materially different process

of using that product (MPEP § 806.05(h)). In the instant case the product could be used to degrade amylase in waste products or possibly even in wallpaper stripper. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required for one Group is not required for another Group particularly in the non-patent literature (when co-classified), restriction for examination purposes as indicated is proper.

Claims 29 is generic to a plurality of disclosed patentably distinct species comprising vast numbers of heterologous proteins especially those set forth in claim 34. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of protein, even though this requirement is traversed if Group IV is elected.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

ELECTION

Applicants provisionally elect Group III, claim 26, drawn to method of treating human acid α-glucosidase deficiency, with traverse.

TRAVERSAL

Applicants respectfully traverse the Examiner's restriction requirement for the following reasons.

The restriction requirement is improper because it omits "an appropriate explanation" as to the existence of a "serious burden" if a restriction were not required. (MPEP § 803). An examination of all the claims in this application would not pose a serious burden because a search of any one of invention Groups I through V would require searching the prior art areas appropriate to the other invention Groups. For example, the art areas identified by the Examiner for each of Groups I, II, III, and IV show identical overlap with each other. Accordingly, it would not pose a serious burden on the Examiner to search each of these Groups.

Additionally, applicants have paid a filing fee for an examination of all the claims in this application. If the Examiner refuses to examine the claims paid for when this application was filed, applicants must pay duplicative fees to file divisional applications for the non-elected or withdrawn groups of claims.

CONCLUSION

In view of the foregoing, applicants respectfully request the Examiner to reconsider and withdraw the restriction requirement and to examine claims 1-37 pending in this application.

If the Examiner has any questions or wishes to discuss this

matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

NATH & ASSOCIATES PLLC

Date: Apr. 17, 2003

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